



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/666,465	09/19/2003	Janusz A. Kuzma	AB-366U	8344

23845 7590 07/11/2006

ADVANCED BIONICS CORPORATION
25129 RYE CANYON ROAD
VALENCIA, CA 91355

EXAMINER

ROBERTS, DARIN

ART UNIT	PAPER NUMBER
----------	--------------

3762

DATE MAILED: 07/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/666,465

Applicant(s)

KUZMA ET AL.

Examiner

Darin R. Roberts

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 and 20-23 is/are pending in the application.
- 4a) Of the above claim(s) 14-19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9, 12, 13, 18, 20, 21 and 23 is/are rejected.
- 7) ☒ Claim(s) 10, 11 and 22 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 11/19/04.
- ☒ Interview Summary (PTO-413)
Paper No(s)/Mail Date 6-22-06.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election by phone without traverse of claims 1-13 & 20-23 in the reply filed on 9/19/03 is acknowledged.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-13 & 20-23, drawn to a method and apparatus, classified in class 607, subclass 137.
- II. Claims 14-19, drawn to process of making, classified in class 29, subclass 590.

Inventions II and I are related as process of making and product made.

The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case Group I is separate and distinct from in group II in that groups I does not require that the electrode contacts onto a substrate, the contacts can be integrally made within or on the substrate.

Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Art Unit: 3762

During a telephone conversation with Mr. Bryant Gold on 6/22/06 a provisional election was made without traverse to prosecute the invention of Group I, claims 1-13 & 20-23. Affirmation of this election must be made by applicant in replying to this Office action. Claims 14-19 were withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under

Art Unit: 3762

the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1 & 2 are rejected under 35 U.S.C. 102(e) as being anticipated by Gibson et al. (US 20030171758 A1).

In reference to **claim 1, 2**, the Gibson et al. patent teaches the use of an implantable lead for use with electrical stimulation (see abstract), the lead comprising an flexible carrier inherently possessing a proximal end, a distal end, a medial side and a lateral side, and a distal curved lead section that is capable of staying curved within the cochlea of the user and inherently possesses at least some memory (see pp. [0051]). The Gibson et al. publication also teaches an electrode array that possess has a plurality of electrode contacts embedded at the distal end of the lead (see pp. [0052]). The array of the Gibson et al. device would inherently possess a means for transferring energy embedded within the carrier (either conductor wires or a functional equivalent of said conductor wires), making contact with the electrodes of the array to transfer energy from the electrodes to the cochlea. Gibson et al. teaches the insertion of a stylet to facilitate the introduction of the electrode carrier, thus the Gibson device must inherently possess a stylet insertion channel in the carrier (see pp. [0015, pp. [0016], & pp. [0055]).

Claims 1-5, 8, & 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Kuzma (US 6119044 A).

Art Unit: 3762

In reference to **claim 1**, the Kuzma patent teaches the use of an implantable lead for use with electrical stimulation (see column 8, lead lines 32-35), the lead comprising an flexible carrier inherently possessing a proximal end, a distal end, a medial side and a lateral side, and a distal curved lead section that is capable of staying curved within the cochlea of the user and inherently possesses at least some memory (see fig. 1 & column 4, lead lines 2-6). The Kuzma device also possesses a plurality of electrode contacts embedded at the distal end of the lead, which electrode contacts comprise an electrode array see (fig. 1 & abstract) and a plurality of conductor wires embedded in the carrier, each conductor wire connected to at least one electrode contact (see column 4, lead lines 53-55). Kuzma teaches a longitudinal stylet insertion channel in the carrier extending into at least a part of the distal, pre-curved lead section (see fig. 4 & abstract).

In reference to **claim 2**, the Kuzma patent teaches a lead of wherein the electrode contacts and connected conductor wires are pre-bent to a desired pre-curvature before the flexible carrier is molded over the electrode contacts and conductor wires (see column 4, lead lines 33-44).

In reference to **claim 3**, the Kuzma patent teaches a lead wherein the distal, pre-curved lead section is dimensionally pre-curved to conform to about one spiral turn in a human cochlear duct (see fig. 16 & abstract), and wherein the distal, pre-curved lead section must inherently possess a curvature, taper and size to provide medial contact with the cochlear duct (see fig. 16).

Art Unit: 3762

In reference to **claim 4**, The Kuzma patent teaches a lead wherein the lead has a distal part that is substantially hooked shaped and has a spiral curvature dimensioned to conform to a human cochlear duct and also to provide lateral contact with this cochlear duct (see fig. 15). Kuzma also teaches a lead inherently possessing a distal, pre-curved lead section that is inherently dimensionally tapered and sized so that the electrode array can be implanted to exceed about 1 turn inside the cochlear duct (see fig. 16).

In reference to **claim 5**, the Kuzma patent teaches a lead wherein the distal lead is inherently dimensionally tapered and sized so that the lead can be implanted no greater than about 2 turns inside the cochlear duct as a result of the shape and dimensions of the cochlear duct, and the portion of the duct being used for insertion is the scala tympani (column 4, lead lines 23-28).

In reference to claim 7, the

In reference to **claims 8 & 9**, the Kuzma patent teaches a device used in conjunction with a lead further comprising an overmolding that caps the stylet channel, and possessing an opening that can be described as a slit to allow for the insertion of stylet (see fig. 14, & column 7, lead lines 1-5).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which

Art Unit: 3762

said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 6, 7, 12, 13, 20 & 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuzma (US 6119044 A).

In reference to **claim 6**, the Kuzma patent teaches a device possessing a distal tip and an array of electrodes within said distal tip (see fig. 4). The Kuzma patent also teaches an implant that tapers toward the distal end and in turn is of a smaller thickness than the more proximal end of the distal portion. The Kuzma patent does not teach a super-flexible electrode-baring tip that does not include the stylet insertion channel.

The Kuzma patent discloses the claimed invention except a super-flexible electrode-baring tip that does not include the stylet insertion channel. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the carrier as taught by the Kuzma patent with the a super-flexible electrode-baring tip that does not include the stylet insertion channel

Art Unit: 3762

since it was known in the art that the use of a super-flexible electrode-baring carrier tip can be used to minimize the amount of damage done to the cochlea during implantation.

In reference to **claim 7**, the Kuzma patent teaches the use of conductor wires within the electrode carrier, the Worley et al patent however does not teach the conductor wires are zigzag.

The Kuzma patent discloses the claimed invention except for the use of zigzag wires. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the carrier as taught by the Kuzma patent with the zigzag conductor wires since it was known in the art that zigzag conductor wires can be used to hinder breakage of the conductor wires.

In reference to **claims 12 & 13**, the Kuzma patent does teach the creation of a stylet insertion channel. The Kuzma patent does not teach the use of a material different from that of the lead, such as Teflon, to construct a stylet insertion channel.

The Kuzma patent teaches the disclosed invention except for the use of a material different from that of the lead, such as Teflon, to construct a stylet insertion channel. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the insertion channel as taught by the Kuzma patent with a material different from the lead itself since it was known in the art that the use of a material with a lower coefficient of friction within the insertion channel can be used to better facilitate the removal of the stylet after insertion.

Art Unit: 3762

In reference to **claim 20 & 21**, the Kuzma et al. teaches a method of implanting an implantable stimulation lead having an insertion stylet channel with a channel opening on the lead body (see abstract). Kuzma also teaches a method comprising implanting the lead using the stylet withdrawing the stylet from the lead (see claim 14). The Kuzma patent does not teach the capping the insertion stylet channel opening using what can be described as a "pin plug".

The Kuzma patent teaches the disclosed invention except for the capping the insertion stylet channel opening using what can be described as a "pin plug". It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the lead body of the Kuzma device with a pin cap since it was known in the art that capping such an orifice of an implantable device is done to prevent the accumulation of infectious material within the body of the channel.

Allowable Subject Matter

Claims 10, 11 & 22 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The Examiner chooses to site **Byers et al (US 4819647 A)** because it is directed toward a cochlear implant device possess an electrode

Art Unit: 3762

array, conduction wires associated with each electrode of said array, as well as a lead that is inherently stiffer at its more proximal end and more flexible at its more distal end.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darin R. Roberts whose telephone number is (571) 272-5558. The examiner can normally be reached on 7:30am to 4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela D. Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-9900.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Darin Roberts
Patent Examiner
Art Unit 3762

George R. Evanisko
Primary Examiner
Art Unit 3762

6/26/6